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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
NIKODEM,D	
ART UNIT	**PAPER NUMBER**
1633	5

DATE MAILED: 09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File

Office Action Summary	Application No.	Applicant(s)	
	09/347,496	XU, JIANGCHUN	
	Examiner	Art Unit	
	David Nikodem	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ 30 days FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-78* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-11, drawn to nucleic acids, vectors encoding nucleic acids, and host cells, classified in classes 536 and 435, subclasses 23.1, 320.1 and 325, respectively.

II. Claims 1-3, 12-15, 28, 33, 52, 55 and 56 drawn to polypeptides, vaccines and/or pharmaceutical compositions comprising said polypeptides, and methods of treating and/or inhibiting colon cancer by administering said polypeptide, classified in classes 530 and 514, subclasses 300, 350, and 2, respectively.

III. Claims 16-19, 29, 33, 43-47, 48, 55 and 56 drawn to methods of treating colon cancer by administering a polynucleotide, and vaccines and pharmaceutical compositions thereof, and method of inhibiting the development of colon cancer by administering said polynucleotide, classified in class 514, subclass 44.

IV. Claims 34-37, 39-42, 47 and 48 drawn to fusion proteins and, vaccines and pharmaceutical compositions thereof, classified in classes 435 and 514, subclasses 350 and 44, respectively.

V. Claim 38, drawn to nucleic acid encoding a fusion protein, classified in class 536, subclass 23.4.

VI. Claims 20, 21, 30, 33 and 71-75 drawn to antibodies, pharmaceutical compositions thereof, kits and methods of inhibiting colon cancer by administering said antibody, classified in class 424, subclasses 130.1 and 159.1.

VII. Claims 49-51, drawn to methods for removing tumor cells from a biological sample and method of using said sample to inhibit cancer development, classified in class 435, subclass 6.

VIII. Claims 52-56 drawn to isolated T cells, a method of expanding T cells and a method of inhibiting cancer development by exposing T cells to polynucleotide, classified in class 435, subclasses 6, 7.1 and 7.21.

IX. Claims 57-60, drawn to method for determining cancer in a patient, classified in class 435, subclass 6.

X. Claims 22-27, 31-33, 52, 55 and 56, drawn to compositions and methods of treating and/or inhibiting cancer comprising antigen presenting cells, and vaccines thereof, classified in class, 424, subclass 93.1.

XI. Claims 61-64, drawn to a method for monitoring the progression of cancer in a patient using a binding agent (protein), classified in class 435, subclasses 6, 7.1 and 7.21.

XII. Claims 65-70 and 76-78, drawn to oligonucleotides and kits thereof, classified in class 536, subclass 24.3.

Note that claims 33, 47, 48, 52, 55 and 56 are in multiple groups and will be examined only to the extent that they read on the elected invention.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, IV and V are distinct in that nucleic acids, polypeptides, fusion proteins and DNA encoding fusion proteins have significantly different structural, physical, and functional properties, can be made using substantially different techniques, and can be used in substantially different methods, such as the use of the nucleic acids to or vectors to generate probes or primers for *in vitro* assays, the use of the proteins in antibody binding assays, and the use of the transformed cells as a therapeutic composition. Further, DNA encoding fusion proteins is structurally and functionally distinct from DNA encoding non-fusion proteins and requires the scientific consideration of non-native protein conformation and/or recombinant techniques to generate said fusion protein.

3. Inventions I and II are related to inventions III and VII-XI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides and polypeptides of inventions I and II can be used in materially processes than the *in vivo* treatment of cancer, such as the use of the polynucleotides *in vitro* hybridization assays and the use of the proteins in *in vitro* antibody binding assays.

4. Invention VI is unrelated to inventions I-V and VII-XII as it involves the use of antibodies for either diagnosing cancer in a sample *in vitro* or for inhibiting cancer *in vivo*. Antibodies are substantially different from proteins, polynucleotides, T cells,

antigen presenting cells, and fusion proteins in structure and function and require different materials and methods to make and/or use.

5. Invention V and VI are unrelated to inventions I-III and VII-XI as they involve the use of fusion proteins and/or DNA encoding said fusion proteins, for either diagnosing cancer in a sample *in vitro* or for inhibiting cancer *in vivo*. Fusion proteins are substantially different from proteins, polynucleotides, T cells, antigen presenting cells in structure and function and require different materials and methods to make and/or use.

6. Inventions V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid coding for the fusion protein can be used as oligonucleotides for PCR and/or *in situ* hybridization.

7. Inventions I, III, and XII are distinct in that the polynucleotides can be used in methods other than diagnosing cancer of treating colon cancer, such as the use of the polynucleotides to transfect cells *in vitro*. Further, the use of polynucleotide primers or probes *in vitro* is significantly different from the administration of polynucleotides *in vivo* to treat cancer in that the primers or probes do not need to be able to express protein as the probes and primers function by binding other polynucleotides, whereas the polynucleotides administered *in vivo* must be able to express a product that can affect cancer in the injected individual. Further, DNA coding for proteins require different

scientific considerations than oligonucleotides used for PCR and/or diagnosis (i.e. expression conditions versus hybridization conditions *in vivo*).

8. Invention III, IX, and XI are distinct in that each uses a significantly different agent to treat cancer. The direct administration of polynucleotides requires the transfection of cells *in vivo* and the expression of the encoded product in a variety of cells types. The administration of T cells transfected with polynucleotides or antigen presenting cells transfected with polynucleotides *ex vivo* requires the acceptance of the potentially foreign cells by the host and limits the expression of the polynucleotide product to the administered T cells or antigen presenting cells. Further, T cells and antigen presenting cells have substantially different activities in the immune response to antigen *in vivo*.

9. Inventions VIII and X are distinct in the each uses a significantly different agent to treat cancer. The administration of T cells pulsed with polypeptides or antigen presenting cells pulsed with polypeptides *ex vivo* requires the acceptance of the potentially foreign cells by the host and limits the presentation of the peptide to the administered T cells or antigen presenting cells. Further, T cells and antigen presenting cells have substantially different activities in the immune response to antigen *in vivo*.

10. Inventions VIII and X are distinct from inventions IX and XI in that cells pulsed with polypeptides receive a finite amount of the peptide which enter the antigen presenting pathway by phagocytosis or endocytosis. On the other hand, cells transfected with polynucleotides continuously produce peptides or proteins which enter the antigen processing pathway through the endoplasmic reticulum. Thus, cells pulsed

with peptide versus cells transfected with polynucleotide have different structural and functional properties.

11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

12. Claims 1-78 are drawn to (or depend upon) nucleotide sequences, polypeptides derived from nucleic acid sequences, nucleotide constructs, and methods requiring the use of nucleotide sequences polypeptides derived from nucleic acid sequences that contain more than ten individual, independent, and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (Nov. 19, 1996).

13. Upon election of one of Inventions I-XI, Applicant is additionally required to select no more than ten of the individual sequences for examination. The search of no more than ten selected sequences may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

14. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

David Nikodem
September 7, 2000

DEBORAH J.R. CLARK
PRIMARY EXAMINER